



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0652]

Draft Guidance for Industry and Food and Drug Administration Staff; the 510(k)

Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)];

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Draft Guidance for Industry and Food and Drug Administration Staff; The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].” FDA developed this draft guidance document to provide a contemporary perspective on how FDA reviews premarket notification (510(k)) submissions as well as on the Special and Abbreviated 510(k) programs. This guidance addresses the major aspects of the 510(k) decision-making process and updates FDA’s policies with respect to the Special and Abbreviated 510(k) programs. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 26, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Draft Guidance for Industry and Food and Drug Administration Staff; The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002 or to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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Center for Biologics Evaluation and Research (HFM-17),

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SUPPLEMENTARY INFORMATION

I. Background

This draft guidance serves to update FDA’s perspective on the Agency’s approach to the 510(k) program, which began in 1976. Since that time, FDA has periodically published guidance that described its approach and any changes therein, to the 510(k) program. On June 30, 1986, FDA published a Blue Book Memorandum titled “Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum #K86-3,” a document which discussed general points regarding the process of determining substantial equivalence between a new device and a predicate device. On March 20, 1998, FDA published another guidance document titled “The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.” This guidance introduced two new 510(k) programs – the Special 510(k) and the Abbreviated 510(k) – as optional approaches available to device manufacturers. This guidance also renamed the original 510(k) program that had been in place since 1976 to the “Traditional 510(k).” Traditional, Special, and Abbreviated 510(k)s differ with respect to the scope and content of information that are included

within the submission. The Special 510(k) is an option for a manufacturer who has made certain changes to a medical device that was previously found substantially equivalent. With this option, the manufacturer relies on conformance with design controls under the Quality System Regulation (21 CFR 820.30) to support substantial equivalence. The Abbreviated 510(k) is an option for manufacturers who rely on guidance documents, special controls, and/or recognized consensus standards to support substantial equivalence. These alternate approaches were intended to streamline FDA's review process and simplify for manufacturers the preparation of a 510(k) that was eligible for these programs. It is noted that the 1986 guidance was issued as final guidance prior to the February 27, 1997, implementation of FDA's Good Guidance Practices (GGPs). Neither guidance has been updated since its initial publication. Upon its issuance as a final guidance document, this new guidance will replace both of those guidances.

In recent years, concerns have been raised both within and outside of FDA about whether the 510(k) program optimally achieves its intended goals. In September 2009, FDA's Center for Devices and Radiological Health (CDRH) convened an internal 510(k) Working Group to conduct a comprehensive assessment of the 510(k) process. The 510(k) Working Group evaluated the 510(k) program with the goal of strengthening the program and improving the predictability, consistency, and transparency of the Agency's decision-making process. On February 18, 2010, the 510(k) Working Group held a public meeting to solicit comments from the public regarding the strengths and challenges associated with the 510(k) program. In August 2010, CDRH published two documents in consideration of the comments made at the public meeting and the Agency's preliminary assessment of the program. These documents are titled "CDRH Preliminary Internal

Evaluations – Volume I: 510(k) Working Group Preliminary Report and Recommendations” and “CDRH Preliminary Internal Evaluations – Volume II: Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations.” In January 2011, CDRH published the “Plan of Action for Implementation of 510(k) and Science Recommendations,” denoting as one of the action items to update the 1998 510(k) Paradigm Guidance.

FDA recognizes and supports efforts for global convergence of regulatory systems, and in particular, through its participation in the Global Harmonization Task Force which published the “Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)” on February 21, 2008. The Agency has specifically considered the STED principles in the FDA Guidance titled “Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s” and has also incorporated those principles in this guidance as appropriate. FDA is specifically interested in seeking comment with respect to how these principles may be further applied in this guidance document and to 510(k) submissions and review generally.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on the 510(k) decision-making process and policies with respect to the 510(k) program. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from CBER at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

To receive “Draft Guidance for Industry and Food and Drug Administration Staff; The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],” you may either send an e-mail request to ds mica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1766 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 56.115 have been approved under OMB control number 0910-0130; the collections of information

found in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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